

902 KAR 20:106. Operation and services; ambulatory surgical center.

RELATES TO: KRS 211.842-211.852, 216B.040, 216B.042, 216B.105(2), (3), 216B.990(1), (2), 311.400, 311.710-311.810, 313.040, 313.420, 314.041, 314.042, 314.051, 333.030

STATUTORY AUTHORITY: KRS 216B.040, 216B.042(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042(1)(a) and (c) require the cabinet to promulgate administrative regulations necessary for the proper administration of the licensure function and to establish licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the licensure requirements for the operation and services of ambulatory surgical centers.

Section 1. Definitions. (1) "Admission" means the time after completion of the registration process and at the first instance of rendering medical care to the patient on the day of the scheduled procedure as a part, or in anticipation, of a surgery.

(2) "Ambulatory surgical center" means a public or private institution that is:

- (a) Hospital based or freestanding;
- (b) Operated under the supervision of an organized medical staff; and
- (c) Established, equipped, and operated primarily for the purpose of treatment of patients by surgery, whose recovery under normal circumstances will not require inpatient care.

(3) "Cabinet" is defined by KRS 216B.015(5).

(4) "Center" means an ambulatory surgical center.

(5) "Licensee" means a person or business entity that has been issued and holds a valid ambulatory surgical center license from the Cabinet for Health and Family Services.

Section 2. Administration and Operation. (1) Licensee.

(a) The licensee shall be legally responsible for operation of the center and for compliance with federal, state, and local laws and regulations pertaining to operation of the center.

(b) The licensee shall develop written policies for the administration and operation of the center. Medical staff shall approve medical policies. Policies shall include.

- 1. Personnel practices and procedures. These shall be available to personnel;
- 2. Job descriptions for each level of personnel including the authority, responsibilities, and actual work to be performed in each classification;
- 3. Written infection control measures. Written procedures shall govern the use of aseptic techniques and procedures in all areas of the center;
- 4. Sterilization of supplies;
- 5. Disposal of patient waste and other potentially infectious materials;
- 6. Examination by a pathologist of tissues removed during surgery. Policies shall identify tissues which require examination and which do not;
- 7. Instances in which consultations with other physicians, dentists, or podiatrists shall be required;
- 8. A list of surgical procedures which may be performed in the center;
- 9. Granting and withdrawal of medical staff surgical privileges and privileges for the administration of anesthetics; and
- 10. Arrangement for transportation of patients who require hospital care.

(2) Personnel.

(a) Administrator. The center shall have an administrator responsible for the day to day operation of the center and for delegating that responsibility in the administrator's absence.

(b) Current employee records shall be maintained and shall include:

- 1. A resume of the employee's training and experience;

2. Evidence of current licensure or registration if required; and
3. Reports of accidents occurring while the employee is on duty.

(c) Medical staff requirements. The center shall have an organized medical staff responsible for the quality of medical care provided in the center and for the ethical and professional practices of its members.

1. The medical staff shall develop the center's medical care policies.
2. Surgical procedures shall be performed by physicians, dentists, or podiatrists who are legally authorized to perform them and have been granted privileges to perform the procedures by the center through its medical staff or governing body.

(d) Pharmaceutical, radiology or laboratory services provided directly by the center or through an agreement with another entity shall be provided under the direction of a licensed pharmacist, a physician specializing as a radiologist, or a physician specializing as a pathologist, respectively, on a full-time, part-time or regular consultative basis.

(e) The center shall employ registered nurses on a full-time basis for patient care in the operating and postanesthesia recovery rooms.

(f) The center shall employ other nursing personnel, aides and technicians as required to meet the needs of the patients served by the center including personnel to be responsible for supervision, indexing, and filing of medical records.

(3) A center shall not retain a patient longer than twenty-four (24) hours from the time of admission to discharge.

(4) The center shall not have provisions for obstetrical deliveries.

(5) Physician coverage. A physician or the practitioner that performs the surgery shall be present in the center until all patients have been discharged and have left the center.

(6) The center shall have a physician on the medical staff with admitting privileges in a nearby hospital who is responsible for admitting patients in need of inpatient care.

(7) Medical records.

(a) Content. Adequate and complete medical records shall be prepared for all patients admitted to the surgical center. Notes shall be legibly written or typed and signed. A medical record shall include the following information:

1. Name and address of person the or agency responsible for the patient;
2. Patient identification data, including the patient's:
 - a. Name;
 - b. Address;
 - c. Age;
 - d. Sex; and
 - e. Marital status;
3. Date of admission and discharge;
4. Referring and attending physicians', dentists' and podiatrists' names;
5. A medical history and physical evaluation that was performed and entered into the medical record no more than thirty (30) days prior to surgery;
6. A surgical consent form that has been signed by the patient or his legal representative prior to the surgical procedure;
7. All preoperative diagnostic studies and laboratory tests;
8. Special examinations, such as consultations, clinical, laboratory, and x-ray;
9. Nurses' notes;
10. Complete medical record signed by the operating surgeon, including:
 - a. Anesthesia record;
 - b. Preoperative diagnosis;
 - c. Operative procedures and findings;

- d. Postoperative diagnosis;
- e. Condition of patient upon discharge;
- f. Postoperative instructions; and
- g. If required, tissue diagnosis by a pathologist on specimens surgically removed;
- 11. Charts including records of temperature, pulse, respiration, and blood pressure; and
- 12. Medication record including:
 - a. Name of medication;
 - b. Dosage;
 - c. Date and time of administration;
 - d. Method of administration;
 - e. Name of prescribing physician, dentist, or podiatrist; and
 - f. Name of person who administered the medication.

(b) Indexing. Medical records shall be systematically filed for ready access by authorized personnel.

(c) Ownership. Records of patients shall not be removed from the center's custody except in accordance with a court order or subpoena. Medical records shall be made available if requested for inspection by duly authorized representatives of the cabinet.

(d) The attending physician, dentist, or podiatrist shall complete and sign the medical record of the patient as soon as practicable after discharge, but not to exceed ten (10) days.

(e) 1. Orders for medication and treatment shall be dated, timed, and signed by the prescribing physician, dentist or podiatrist, or the health care practitioner who receives the verbal order.

2. Verbal orders shall be countersigned by the prescribing physician, dentist, or podiatrist within forty-eight (48) hours, except that records for Schedule II drugs shall be signed immediately.

3. A record of medication administered to the patient shall be included in the record and signed by the person administering the medication.

(f) Retention of records. Medical records shall be retained for a minimum of five (5) years or, in the case of a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

(8) Bedrails shall be available for patients in the admitting and recovery units.

Section 3. Sanitary Environment. The surgical center shall provide a sanitary environment to avoid sources and transmission of infections.

(1) An infection committee composed of members of the medical and nursing staff shall be established and be responsible for controlling and preventing infections within the center.

(2) Nondisposable sterile supplies shall be reprocessed if the integrity of the pack has not been maintained.

(3) The center shall have suitable equipment for rapid and routine sterilization of supplies, utensils and equipment and shall store them in a clean, convenient and orderly manner.

(4) Continuing education shall be provided to all surgical center personnel on the cause, effect, transmission, prevention and elimination of infections.

Section 4. Surgical Services. (1) The center shall provide treatment of patients by surgery, whose recovery under normal circumstances will not require inpatient care.

(2) The center shall have at least one (1) operating room.

(3) A patient shall be examined by a physician, dentist, or podiatrist acting within the professional's scope of practice immediately prior to surgery to evaluate the risk of anesthesia and the risk of the procedure to be performed.

(4) A registered nurse shall be available to circulate at all times. The operating rooms shall be supervised by a registered nurse.

(5) The center shall have on file a list of all physicians, dentists and podiatrists with surgical privileges at the center and the privileges assigned to each by the medical staff.

(6) The center shall maintain a complete and up-to-date operating room register.

(7) The following equipment shall be available in the center:

(a) Oxygen;

(b) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator;

(c) Cardiac defibrillator;

(d) Cardiac monitoring equipment;

(e) Tracheostomy set;

(f) Laryngoscopes and endotracheal tubes;

(g) Suction equipment; and

(h) Emergency medical equipment and supplies specified by the medical staff.

(8) The center shall have arrangements for obtaining an adequate supply of blood in a timely manner to meet the center's needs.

(9) A physician's, dentist's, or podiatrist's orders shall be in writing and signed by the physician, dentist, or podiatrist.

(10) Except for cases requiring only local infiltration anesthetics, a physician anesthesiologist, a physician qualified to administer anesthesia, a dentist qualified to administer anesthesia, or a registered nurse anesthetist acting under the direction of the operating surgeon shall administer the anesthetics and remain present during the surgical procedures and until the patient is fully recovered from the anesthetics.

(11) The physician, dentist, or podiatrist in charge of the patient shall be responsible for seeing that tissue removed during surgery is delivered to the center's pathologist and that an examination and report is made on the tissue, if required by the center's written policies.

(12) Voluntary interruption of pregnancies. An ambulatory surgical center shall comply with the applicable Kentucky statutes concerning the voluntary interruption of pregnancies, including KRS 311.710 to 311.810.

Section 5. Postanesthesia Recovery Services. (1) The center shall have at least one (1) postanesthesia recovery unit

(2) There shall be adequate staff available in the recovery unit so that no patient is left alone at any time.

(3) A registered nurse shall be present in the recovery unit when a patient is recovering from anesthesia.

(4) A registered nurse shall be available to the recovery unit at all times.

(5) A person staffing the postanesthesia recovery unit shall be adequately trained in all aspects of postoperative and postanesthetic care.

(6) The recovery unit nurse shall record a nursing note on a patient, noting the following:

(a) Postoperative abnormalities or complications;

(b) Pulse;

(c) Respiration;

(d) Blood pressure;

(e) Presence or absence of swallowing reflex;

(f) Cyanosis; and

(g) The general condition of the patient.

(7) Available equipment shall include the following:

- (a) Suction machine;
- (b) Stethoscope;
- (c) Sphygmomanometer;
- (d) Emergency crash cart;
- (e) Necessary drugs; and
- (f) Oxygen.

(8) The surgical center shall provide suitable accommodations for its patients. There shall be adequate floor space, furnishings, bed linens, and other utensils, equipment and supplies reasonably required for the proper care of the patients accommodated.

Section 6. Pharmaceutical Services. (1) The center shall have a licensed pharmacy or have arrangements for promptly obtaining prescribed drugs and biologicals from a pharmacy.

(2) The center shall provide appropriate methods and procedures for storage, control and administration of drugs and biologicals, developed with the advice of a licensed pharmacist. The pharmacist shall properly label drugs for individual patients.

(3) Licensed medical or nursing personnel shall administer medications in accordance with the established standards of practice set forth for:

- (a) Podiatrists licensed in accordance with KRS 311.400;
 - (b) Physicians licensed in accordance with KRS 311.571;
 - (c) Dentists licensed in accordance with KRS 313.040 or 313.045;
 - (d) Dental specialists licensed in accordance with KRS 313.420; or
 - (e) Nurses licensed in accordance with KRS 314.041, 314.042, or 314.051.
- (4) Controlled substances.

(a) Controlled substances shall be kept under double lock (i.e., in a locked box in a locked cabinet). There shall be a controlled substances record in which is recorded the:

- 1. Name of the patient;
- 2. Date and time;
- 3. Kind of controlled substance;
- 4. Dosage and method of administration of the controlled substance;
- 5. Name of the physician who prescribed the controlled substance; and
- 6. Name of the nurse who administered it.

(b) In addition to the requirements established in paragraph (a) of this subsection, there shall be a recorded and signed:

- 1. Schedule II controlled substances count daily conducted by a member of the nursing staff; and
- 2. Schedule III, IV, and V controlled substances count once per week by a member of the nursing staff.

Section 7. Radiology Services. (1) The center shall provide radiology services directly through an agreement with a licensed hospital, or through an independent radiology service.

(2) The radiology service shall have a current license or registration pursuant to KRS 211.842 to 211.852.

(3) If radiology services are provided directly by the center:

(a) The radiology department shall be free of hazards for patients and personnel. Proper safety precautions shall be maintained against;

- 1. Fire and explosion hazards;
- 2. Electrical hazards; and
- 3. Radiation hazards;

(b) A physician specializing in radiology shall supervise the department and interpret films

that require specialized knowledge for accurate reading;

(c) Signed reports shall be promptly entered into the medical record and duplicate copies kept in the department; and

(d) Orders for radiology procedures shall be made by a physician, dentist or podiatrist.

Section 8. Laboratory Services. (1) The center shall provide laboratory services directly through its own licensed laboratory, through an agreement with a laboratory in a licensed hospital, or through an agreement with a licensed laboratory nearby.

(2) The medical laboratory providing services to the center shall be licensed pursuant to KRS 333.030, unless it is a part of a licensed hospital.

(3) Laboratory examinations shall be made only upon the request of a physician, dentist, or podiatrist.

(4) The laboratory shall provide tissue pathology and diagnostic cytology examinations. Tissues removed from a patient during surgery shall be examined by a physician specializing in pathology if required by the center's written policies.

(5) Laboratory and tissue pathology reports shall be signed and entered into the medical record.

Section 9. Utilization Review. (1) The surgical center shall have in effect a plan for utilization review of their services on at least a quarterly basis by a committee of physicians, dentists, or podiatrists who have no financial interest in the center.

(2) Reviews shall be made of admissions and professional services furnished including utilization of surgical services and tissue reports. (8 Ky.R. 251; eff. 11-5-81; Am. 12 Ky.R. 611; eff. 12-10-85; 18 Ky.R. 824; eff. 10-16-91; 32 Ky.R. 1152; 1400; eff. 3-2-2006; 35 Ky.R. 1919; 2443; eff. 6-5-09.)